

Preferred Drug List Committee Meeting

Meeting Minutes, Open Session

June 13, 2018 11:30 a.m.

DXC Technologies-Capital Room, 6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619

Board Members Present:

Donna Sweet, M.D., MACP (Chair)(Phone)

Megan Hedden, Pharm.D.

Sharon Cain, M.D.

Taylor Gill, Pharm. D., BCPS, AAHIVP (Interim Chair)

Emily Prohaska, Pharm.D., BCACP (Phone)

Raymond Magee, M.D.

Wayne Wallace, M.D.

Board Members Absent:

Robert Haneke, Pharm.D.

KDHE-DHCF Staff:

Annette Grant, RPh

Roxanne Chadwell, PharmD, CSP

Carol Arace, Sr. Admin. Asst.

DXC Staff Present:

Ellen McCaffrey, RN, BSN

Kathy Kaesewurm, RN, BSN

HID Staff Present:

None

MCOs Present:

Jennifer Murff-United Healthcare

Angie Zhou-Sunflower

Lisa Todd-Amerigroup

Public Attendees:

Josephine Garcia-Ferrer, Achelion; Meghan Vemgan, Merck; Chris Stanfeild, Supernus; Luke Weedon, Sage; Rick Keylar, Otsuka; Melissa Basil, Abbvie; Ryan Pierre; Phil King, Pfizer; Jim Baumann, Pfizer; Scott Maurice, Boehringer; Michele Puyear, Gilead; Jennifer Stoffel, Janssen; Berend Koops, Merck; Terry McCurn, Otsuka; Elizabeth Ariano, Indinus.

Item	Facilitator (s)	Notes
I. Call to Order	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Dr. Gill called the June 13, 2018 PDL Committee meeting to order at 11:30am. Dr. Gill requested introductions from all at the table and introduced Susan Cain as a new member of the PDL Committee. Dr. Gill notified the attendees about public comment with the length of time to make a public comment being less than five minutes. She also requested that if anyone wishes to make a public comment, they must fill out and turn in to her the <u>Conflict of Interest form</u> prior to speaking.
I. Call to Order A. Announcements	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Dr. Gill requested introductions from all at the table and introduced Susan Cain as a new member of the PDL Committee. Ms. Grant reminded everyone about the possible towing if anyone has parked south of the building. Dr. Gill notified the attendees about public comment with the length of time to make a public comment being less than five minutes. She also requested that if anyone wishes to make a public comment, they must fill out and turn in to her the Conflict of Interest form prior to speaking.
II. Old Business A. Review and Approval of March 14, 2017 Minutes	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	The draft minutes from the March 14, 2017 meeting were reviewed. Dr. Sweet moved to approve the minutes. Dr. Magee seconded the motion. The motion carried unanimously, and the minutes were approved.
II. Old Business B. Consent Agenda Items i. PDL New Drug Placements 1. Zioptan® Droperette 2. Nexium® kit 3. Xyzal® solution	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Background: At the September 13, 2017 PDL meeting the Committee agreed to the 'Consent Agenda Items' old business. 'Pre-approval for drug molecule dose form, dose device, IR/ER, and strength of a current PDL drug with the State providing 'Consent Agenda Items' with a list of agents, under 'Old Business' as a report to the Committee at each PDL meeting.' The list would be titled "Appendix A*". Public Comment: None Committee Discussion: Dr. Wallace moved to approve Appendix A. Dr. Sweet seconded the motion. The motion carried unanimously. *Appendix A follows the minutes below.
III. New Business A. Pulmonary (Arterial)	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Background: This class was established at the March 2017 PDL meeting and currently includes Adcirca,

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<p>Hypertension: New Agents- (Ventavis®, Remodulin®, Tyvaso®, Tyvaso® Refill & Starter Kit)</p> <ul style="list-style-type: none"> i. Public Comment ii. Committee Discussion/Recommendations 		<p>Letairis, Tracleer, Adempas, Opsumit, Orenitram ER, Revatio, Uptravi. Three possible additions to the class are presented for review today. The first is Ventavis® (iloprost), an inhaled synthetic prostacyclin (PGI₂), the second is Remodulin® (treprostinil), an injectable formulation of the prostacyclin treprostinil, and the third is Tyvaso® and Tyvaso® Refill and Starter Kit (treprostinil), an inhaled formulation of treprostinil. These prostacyclin agents work by causing vasodilation of pulmonary and systemic arterial vascular beds and inhibiting platelet aggregation. Included for the board today are package inserts of all agents in the class and a class comparison chart.</p> <p>Public Comment: Josephine Garcia-Ferrer with Actelion Pharmaceuticals spoke on behalf of Opsumit and Uptravi.</p> <p>Committee Discussion: The Committee commented on the size of Class and requested information on possible splitting the class into separate groups. Ms. Grant noted the State as a preferred agent per mechanism and will wait until there is enough competition among all mechanism before splitting this Class.</p> <p>Dr. Wallace moved to approve. Dr. Magee seconded the motion. The motion carried unanimously.</p>
<p>III. New Business B. ACE Inhibitor/Calcium Channel Blocker Combinations: New Agent- (Prestalia®)</p> <ul style="list-style-type: none"> i. Public Comment ii. Committee Discussion/Recommendations 	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p>Background: This class was first established in March 2007 and is seeking review for the recently approved combination drug Prestalia® (perindopril/amlodipine). A class comparison chart and package inserts are included for the committee's review.</p> <p>Public Comment: None.</p> <p>Committee Discussion: Dr. Magee moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.</p>
<p>III. New Business C. Corticosteroids – Oral: New Class- (Rayos®,</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p>Background: This is a new class presented for inclusion to the PDL today. It includes different formulations of prednisone or prednisolone, which are corticosteroids used to treat a variety of</p>

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<p>Millipred®, Millipred® DP, Millipred® DP 12 day, Veripred® 20, Deltasone®, Orapred®, Orapred® ODT, Pediapred®, Prednisone Intensol®)</p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>		<p>inflammatory conditions. A class comparison chart and package inserts are included for the committee's review.</p> <p>Public Comment: None.</p> <p>Committee Discussion: Ms. Grant provided clarification for the utilization of significant agents that were high cost and need to be monitored more closely. There are preferred prednisone and prednisolone agents. The Committee mention other agents they felt should be in this class. The State will bring the class back with the other agents for consideration at the next PDL meeting.</p> <p>Dr. Wallace moved to approve. Dr. Magee and Dr. Sweet seconded the motion. The motion carried unanimously.</p>
<p>III. New Business</p> <p>D. Inflammatory Bowel Disease Agents – Oral – Class Review – New Agents: (Azulfidine® EN, Entocort® EC)</p> <p>i. Public Comment</p> <p>ii. Committee Discussion/Recommendations</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p>Background: This class was last reviewed at the March 2017 PDL meeting and currently includes Apriso, Asacol HD, Azulfidine, Colazal, Delzicol, Dipentum, Giazol, Lialda, Pentasa, and Uceris. Azulfidine® EN is a delayed release (enteric-coated) formulation of sulfasalazine. Entocort® EC is an enteric-coated formulation of budesonide. A class comparison chart and package inserts are included for the committee's review. Although these are not new agents, there is significant utilization and addition to the PDL would make a more complete class listing.</p> <p>Public Comment: None.</p> <p>Committee Discussion: Dr. Magee moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.</p>
<p>III. New Business</p> <p>E. Alpha2 Agonists – Ophthalmic – New Class: (Qoliana®, Alphagan® P, Brimonidine 0.2%, Iopidine®)</p> <p>i. Public Comment</p>	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p>Background: This class was originally presented for inclusion to the PDL in March 2016, however it was not brought to the DUR Board, due to vacancy of a Medicaid Pharmacy Program Manager, causing a break in the approval process. Since that time Qoliana® has become available. If the class is approved at the June 2018 PDL meeting, presentation to the DUR Board would be made in July. Ophthalmic formulations of Alpha 2 Agonists are used for treating glaucoma as well as other conditions that cause intraocular hypertension. A class comparison chart and package inserts are included for the committee's review.</p>

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ii. Committee Discussion/Recommendations		Public Comment: None. Committee Discussion: Dr. Magee moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business F. Beta-Blockers – Ophthalmic – New Class: (Betagan®, Betimol®, Betoptic®-S, Istalol®, OptiPranolol®, Timoptic®, Timoptic®-XE, Timoptic® Ocudose, Metipranolol, Carteolol) i. Public Comment ii. Committee Discussion/Recommendations	<i>Taylor Gill, Pharm. D., BCPS, AAHVP</i>	Background: This class was originally presented for inclusion to the PDL in March 2016, however it was not brought to the DUR Board, due to vacancy of a Medicaid Pharmacy Program Manager, causing a break in the approval process. If the class is approved at the June 2018 PDL meeting, presentation to the DUR Board would be made in July. Ophthalmic formulations of Beta Antagonists are used for treating glaucoma as well as other conditions that cause intraocular hypertension. A class comparison chart and package inserts are included for the committee’s review. Public Comment: None. Committee Discussion: Dr. Wallace moved to approve. Dr. Sweet seconded the motion. The motion carried unanimously.
III. New Business G. Glaucoma Combination Agents – Ophthalmic – New Class: (Combigan®, Cosopt®, Cosopt® PF, Simbrinza®) i. Public Comment ii. Committee Discussion/Recommendations	<i>Taylor Gill, Pharm. D., BCPS, AAHVP</i>	Background: This is a new class presented for inclusion to the PDL today. It includes different formulation combinations of brimonidine (alpha 2 agonist), timolol (beta blocker), and/or dorzolamide or brinzolamide (carbonic anhydrase II inhibitor) to reduce intraocular pressure in patients whose glaucoma symptoms are not controlled with a single agent. A class comparison chart and package inserts are included for the committee’s review. Public Comment: None. Committee Discussion: Simbrinza® will be removed from it’s current ‘single agent’ class and kept only in this Combination Class. Dr. Magee moved to approve as amended.

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		Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business H. Erythropoiesis Stimulating Agents – Class Review – New Agent: (Mircera®) i. Public Comment ii. Committee Discussion/Recommendations	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Background: This class was first established in December 2008 and is currently seeking review for the FDA approved drug Mircera®. Mircera® is an injectable formulation of methoxy polyethylene glycol-epoetin beta used for the treatment of anemia associated with chronic kidney disease for adult patients including those on dialysis. A class comparison chart and package inserts are included for the committee’s review. Public Comment: None. Committee Discussion: Dr. Sweet moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business I. Immunomodulation Agents – Juvenile Idiopathic Arthritis – Class Review – New Agent: (Ilaris®) i. Public Comment ii. Committee Discussion/Recommendations	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Background: This class was last reviewed in March 2017 and currently includes Actemra, Enbrel, Humira, and Orencia. Ilaris® (canakinumab) is an interleukin-1 beta inhibitor indicated for the treatment of active systemic juvenile idiopathic arthritis, as well as a variety of other auto-inflammatory periodic fever syndromes for both pediatrics and adults. A class comparison chart and package inserts are included for the committee’s review. Public Comment: None. Committee Discussion: Dr. Magee moved to approve. Dr. Cain seconded the motion. The motion carried unanimously.
III. New Business J. Immunomodulation Agents – Plaque Psoriasis – Class Review – New Agent: (Ilumya®) i. Public Comment	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Background: This class was last reviewed in September 2017 for the inclusion of Tremfya and currently includes Amevive, Cosentyx, Enbrel, Humira, Otezla, Remicade, Siliq, Stelara, and Taltz. Ilumya® (tildrakizumab-asmn) is a new interleukin-23 antagonist administered as a subcutaneous injection. A class comparison chart and package inserts are included for the committee’s review.

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ii. Committee Discussion/Recommendations		Public Comment: None. Committee Discussion: Dr. Sweet moved to approve. Dr. Cain seconded the motion. The motion carried unanimously.
III. New Business K. Class Name Change Request – Methotrexate – Injectable to Methotrexate Products — New Agents: (Xatmep®, Trexall®, generic Rheumatrex®) i. Public Comment ii. Committee Discussion/Recommendations	Taylor Gill, Pharm. D., BCPS, AAHIVP	Background: This class was first introduced in May 2015 regarding solely the injectable formulations of methotrexate - Otrexup and Rasuvo. The inclusion of additional formulations currently available is being requested, along with a class name change to Methotrexate Products. The new agents to this class would include Trexall®, an oral tablet formulation, Rheumatrex®, which is supplied as a pre-determined dose pack and Xatmep®, an oral solution formulation. A class comparison chart and package inserts are included for the committee’s review. Public Comment: None. Committee Discussion: Dr. Magee moved to approve class name change and to add the three agents. Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business L. Statins – Class Review – New Agent: (Zypitameg®) i. Public Comment ii. Committee Discussion/Recommendations	Taylor Gill, Pharm. D., BCPS, AAHIVP	Background: This drug class was last reviewed in March 2017 and is being presented today with the recent approval of Zypitameg® (pitavastatin). Zypitameg has the same active ingredient as Livalo, but is now available as a magnesium salt. A class comparison chart and package inserts are included for the committee’s review. Public Comment: None. Committee Discussion: Dr. Magee moved to approve. Dr. Cain seconded the motion. The motion carried unanimously.
III. New Business M. Non-Steroidal Atopic Dermatitis – New Class:	Taylor Gill, Pharm. D., BCPS, AAHIVP	Background: This is a new class presented for inclusion to the PDL today. Eucrisa® (crisaborole) is a phosphodiesterase-4 inhibitor, while Elidel® (pimecrolimus) and Protopic® (tacrolimus) are

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<p>(Eucrisa®, Protopic®, Elidel®)</p> <ul style="list-style-type: none"> i. Public Comment ii. Committee Discussion/Recommendations 		<p>calcineurin inhibitors. All 3 medications are topical agents indicated for the treatment of atopic dermatitis in adults and children 2 years of age and older. A class comparison chart and package inserts are included for the committee's review.</p> <p>Public Comment: Phil King with Pfizer spoke on behalf of Eucrisa®.</p> <p>Committee Discussion: Dr. Sweet moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.</p>
<p>III. New Business</p> <p>N. Corticosteroids – Topical - High Potency – Class Review – New Agent: (Impoyz®)</p> <ul style="list-style-type: none"> i. Public Comment ii. Committee Discussion/Recommendations 	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p>Background: Clobetasol Propionate has been reviewed and approved under this class at multiple dates for a variety of strengths and formulations. It is being requested that Impoyz® be reviewed and considered for inclusion on the PDL today. The addition of Impoyz would expand the approval of clobetasol to include the 0.025% strength, which is available as a cream. Included for the committee's review are the package inserts and a class comparison chart.</p> <p>Public Comment: None.</p> <p>Committee Discussion: Dr. Sweet moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.</p>
<p>III. New Business</p> <p>O. Desmopressin Products (all routes and dose forms) – New Class: (Noctiva®, DDAVP®, DDAVP® Rhinal Tube)</p> <ul style="list-style-type: none"> i. Public Comment ii. Committee Discussion/Recommendations 	<p><i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i></p>	<p>Background: This is a new class presented for inclusion to the PDL today. Desmopressin is the man-made form of a naturally occurring hormone that regulates how the body uses water. It is commonly used to treat frequent urination (bedwetting) among other purposes and is available in a variety of strengths and formulations. Included for the committee's review are the package inserts and a class comparison chart.</p> <p>Public Comment: None.</p> <p>Committee Discussion: Dr. Magee moved to approve. Dr. Cain seconded the motion.</p>

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		The motion carried unanimously.
III. New Business P. Opioids-Short Acting – Class Review – New Agent: (Apadaz®) i. Public Comment ii. Committee Discussion/Recommendations	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Background: The Short-Acting Opioids class was first introduced to the PDL committee as a new class in December 2017 and again in March 2018. This proposition requests the addition of single agent Apadaz® (Benzhydrocodone/Acetaminophen). Opioids are medically indicated for the reduction of both acute and chronic pain. Opioids work primarily through binding to the opioid mu-receptors in the brain, spinal cord, and smooth muscle. Binding of the opioid mu-receptor results in analgesia, euphoria, miosis, reduced GI motility, and respiratory depression. Included for the committee’s review are the package inserts and a class comparison chart. Public Comment: None. Committee Discussion: Dr. Wallace approve. Dr. Magee seconded the motion. The motion carried unanimously.
IV. Open Public Comment	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	None.
V. Adjourn	<i>Taylor Gill, Pharm. D., BCPS, AAHIVP</i>	Dr. Gill adjourned the meeting at 12:24pm.

Appendix A

March 2018 Consent Agenda Item List

This PDL option/process was approved 09/13/2017 by the PDL Committee and 10/11/2017 by the DUR Board.

Drug Proposed - Consent Agenda Item	Compare Drug	Supporting information	Meeting Date listed on the PDL Agenda	PDL Committee Approval Yes/No
Zioptan Droperette	Zioptan		6/13/2017	Yes
Nexium kit	Nexium		6/13/2017	Yes
Xyzal Solution	Xyzal		6/13/2017	Yes